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EXAMINER
DAVIS, MINH TAM B

ART UNIT	PAPER NUMBER
1642	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/991,681	BILLING-MEDEL ET AL.	
	Examiner	Art Unit	
	MINH-TAM DAVIS	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 June 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17-24,34,36 and 37* is/are pending in the application.

4a) Of the above claim(s) *20-24,34,36 and 37* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Applicant's election without traverse of group I, claims 17-19, species the full length sequence of SEQ ID NO:27, in Paper No. 6 is acknowledged.

It is noted that since the species SEQ ID NO:27 is free of prior art, the fragment species SEQ ID Nos: 28-31 are rejoined with the species SEQ ID NO:27.

Accordingly, group I, claims 17-19, SEQ ID NOs:27-31 and fragments thereof, are examined in the instant application.

OJBECTION

The preliminary amendment of paper No:3 on 11/26/01 is objected to, because in this amendment, Applicant requests to cancel claims 1-16, 25-33, 35, 38, 39 of the parent file, application SN=09/065383. It is noted that each application is examined independently of each other.

REJECTION UNDER 35 USC 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 17 is rejected under 35 USC 101 because the claim is directed to non-statutory subject matter.

Claim 17 is drawn to a PS118 polypeptide having at least 50% identity with an amino acid sequence selected from the group consisting of SEQ ID NO:27-31 and fragments thereof.

The polypeptide as claimed has the same characteristics and utility as a polypeptide found naturally and therefore do not constitute patentable subject matter. In the absence of the hand of man, the naturally occurring polypeptide is considered non-statutory subject matter. Diamond v. Chakrabarty, 206 USPQ 193 (1980). Amendment of the claims to recite " an isolated polypeptide" is suggested to overcome this rejection.

REJECTION UNDER 35 USC 101, UTILITY

35 U.S.C. 101 reads as follows:

> "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

Claims 17-19 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific, substantial asserted utility or a well established utility.

Claims 17-19 are drawn to a PS118 polypeptide having at least 50% identity with an amino acid sequence selected from the group consisting of SEQ ID NO:27-31 and fragments thereof. Said polypeptide is produced by recombinant or synthetic techniques.

The disclosed utilities for the full length polypeptide of SEQ ID NO: 27, and fragments thereof comprising SEQ ID NO:28-31, include diagnosis, and treatment of prostate tissue diseases associated with expression of SEQ ID NO:27, including prostate cancer, drug screening (specification, pages 33, 35, 36), and production of and screening of agonists, antibodies and antagonists that specifically bind to SEQ ID NO:27 (specification, Example 14 on p.78). However, neither the specification nor any art of record teaches what SEQ ID NO:27 is, what it does do; they do not teach a utility for any of the fragments claimed; they do not teach a relationship to any specific diseases or establish any involvement in the etiology of any specific diseases.

The asserted utilities for SEQ ID NO:27-31, such as production of and screening of agonists, antibodies and antagonists apply to many unrelated polypeptide structure sequences. Therefore the asserted utilities are not considered "specific" utilities, i.e. they are not specific to SEQ ID NO:27-31.

Additional disclosed utilities for SEQ ID NO:27-31 include diagnosis, and treatment of prostate diseases associated with expression of SEQ ID NO:27-31, including prostate cancer. The asserted utilities are based on the following disclosure: The PS118 polypeptide of SEQ ID NO:27 is a predicted polypeptide sequence encoded by an EST consensus sequence of SEQ ID NO:10, which is obtained from a prostate library (specification, Example 1 and p.54). Further, on Western blots, an antibody to SEQ ID NO:31, which is a fragment of SEQ ID NO:27, detects two bands of 66 kD and 96 kD, which are over-expressed in prostate cancer and benign prostate hyperplasia (BPH), as compared to breast, bladder, lung and colon tissue (specification, Example

16, pages 83-84, and figure 5). There is however no control data concerning expression of SEQ ID NO:27 or fragments thereof in normal prostate tissue. The specification contemplates the use of gene therapy, and antisenses of PS118 polynucleotide for treating prostate tissue diseases associated with expression of PS118, including prostate cancer (specification, p.33). The specification further contemplates use of PS118 polynucleotide and polypeptide as markers of prostate tissue diseases, including prostate cancer (specification, p. 36, 88), and use of antibodies specific for PS118 polypeptide for treating prostate tissue diseases, including prostate cancer (specification, p. 35).

It is noted that the claimed PS118 polypeptide of SEQ ID NO:27 would not be suitable as markers for prostate tissue diseases, including prostate cancer. Without any control data concerning expression of SEQ ID NO:27 in normal prostate tissue, one could not reasonably conclude that the claimed PS118 polypeptide of SEQ ID NO:27 is overexpressed in prostate cancer as compared to the control normal prostate tissue, because the level of protein expression of a gene in a certain tissue such as normal prostate tissue, is not predictable. Keesee, S et al, 1996, Critical Rev Eukaryotic gene expression, 6(2-3): 189-214) teach that the ideal tumor markers is defined by several characteristics: It should be produced by tumor cells and should be detected in body fluids or in tissue. It should not be detected in healthy individuals or in those with benign deseases. It should be present in adequate amounts and early enough in the course of disease to be useful in screening for the particular cancer that it identifies. The level of the marker found in circulation should bear a direct relationship to tumor burden, and

should be detectable even when the tumor is not clinical evident. Last, the circulating level of the marker should correlate with the results of therapy directed at the eradication of the tumor (p.190, second column, second paragraph). Thus based on the teaching of Keesee et al, the data disclosed in the present application do not seem meet the criteria for markers of a tumor. At most the Western blots data indicate that SEQ ID NO:27 is overexpressed in prostate tissue as compared to other tissues. However, over-expression in a specific organ or being specific to a specific organ does not confer specific utility, because such property is shared by different prostate specific polypeptides or polynucleotides, the structure and function of which are not related to SEQ ID NO:27 or the encoding polynucleotides thereof.

Moreover, one cannot reasonably conclude that SEQ ID NO:27-31 or the encoding polynucleotides thereof could be used for treating prostate tissue disease or prostate cancer. Based on the Western blot data, it is unlikely that SEQ ID NO:27 or the encoding polynucleotides thereof is responsible for prostate cancer cell growth, because overexpression in prostate cancer as compared to other tissues does not necessarily confer any growth regulation property of prostate cancer cells. Further, it is unlikely that SEQ ID NO:27 or the encoding polynucleotides thereof could be used for treating prostate tissue diseases, including prostate cancer, because not only there is no correlation between overexpression of SEQ ID NO:27 in prostate cancer as compared to other tissues and growth regulation of the prostate, but also because of the unpredictability of cancer treatment, and gene therapy.

It is well known that the art of anticancer drug discovery for cancer therapy is highly unpredictable, for example, Gura (Science, 1997, 278:1041-1042) teaches that researchers face the problem of sifting through potential anticancer agents to find ones promising enough to make human clinical trials worthwhile and teach that since formal screening began in 1955, many thousands of drugs have shown activity in either cell or animal models but that only 39 have actually been shown to be useful for chemotherapy (p. 1041, see first and second para). Because of the known unpredictability of the art, in the absence of experimental evidence, no one skilled in the art would accept the assertion that the claimed polypeptides of SEQ ID NO:27-31 would be useful for treating prostate cancer. Further, the refractory nature of cancer to drugs is well known in the art. Jain (Sci. Am., 1994, 271:58-65) teaches that tumors resist penetration by drugs (p.58, col 1) and that scientists need to put expanded effort into uncovering the reasons why therapeutic agents that show encouraging promise in the laboratory often turn out to be ineffective in the treatment of common solid tumors (p. 65, col 3). Curti (Crit. Rev. in Oncology/Hematology, 1993, 14:29-39) teaches that solid tumors resist destruction by chemotherapy agents and that although strategies to overcome defense mechanisms of neoplastic cells have been developed and tested in a number of patients, success has been limited and further teaches that it is certainly possible that cancer cells possess many as yet undefined additional molecular mechanisms to defeat chemotherapy treatment strategies and if this is true, designing effective chemotherapeutic regimens for solid tumors may prove a daunting task (para bridging pages 29-30) and concludes that knowledge about the physical barriers to drug delivery

in tumors is a work in progress (p. 36, col 2). It is clear that based on the state of the art, in the absence of experimental evidence, no one skilled in the art would accept the assertion that the claimed polypeptides of SEQ ID NO:27-31 would be useful for treating prostate cancer. In addition, Hartwell et al (Science, 1997, 278:1064-1068) teach that an effective chemotherapeutic must selectively kill tumor cells, that most anticancer drugs have been discovered by serendipity and that the molecular alterations that provide selective tumor cell killing are unknown and that even understanding the detailed molecular mechanism by which a drug acts often provides little insight into why the treated tumor cell dies (para bridging pages 1064-1065) and Jain (cited supra) specifically teaches that systemic treatment typically consists of chemotherapeutic drugs that are toxic to dividing cells (p. 58, col 2, para 2).

Further, the state of the art at the time of filing was that the combination of vector, promoter, protein, cell, target tissue, level of expression and route of administration required to target the tissue of interest and obtain a therapeutic effect using gene therapy was unpredictable. For example, Miller (1995, FASEB J., Vol. 9, pages 190-199) review the types of vectors available for *in vivo* gene therapy, and conclude that "for the long-term success as well as the widespread applicability of human gene therapy, there will have to be advances...targeting strategies outlined in this review, which are currently only at the experimental level, will have to be translated into components of safe and highly efficient delivery systems" (page 198, column 1). Deonarain (1998, Expert Opin. Ther. Pat., Vol. 8, pages 53-69) indicate that one of the biggest problems hampering successful gene therapy is the "ability to target a gene to a

significant population of cells and express it at adequate levels for a long enough period of time" (page 53, first paragraph). Deonarain reviews new techniques under experimentation in the art which show promise but states that such techniques are even less efficient than viral gene delivery (see page 65, first paragraph under Conclusion section). Verma (Sept. 1997, Nature, Vol. 389, pages 239-242) reviews vectors known in the art for use in gene therapy and discusses problems associated with each type of vector. The teachings of Verma indicate a resolution to vector targeting has not been achieved in the art (see entire article). Verma also teaches appropriate regulatory elements may improve expression, but it is unpredictable what tissues such regulatory elements target (page 240, sentence bridging columns 2 and 3). Crystal (1995, Science, Vol. 270, page 404-410) also reviews various vectors known in the art and indicates that "among the design hurdles for all vectors are the need to increase the efficiency of gene transfer, to increase target specificity and to enable the transferred gene to be regulated" (page 409).

Further, concerning the use of the claimed SEQ ID NO:27-31 or the encoding polynucleotides thereof for drug screening, for a utility to be "well-established" it must be specific, substantial and credible. In this case, neither the toxic substances nor the susceptible organ systems are identified from drug screening using the claimed probes. Therefore, drug screening is a utility which would apply to virtually every member of a general class of materials, such as any collection of proteins or DNA, but is only potential with respect to SEQ ID NO: 27-31. Because of this, such a utility is not specific and does not constitute a "well-established" utility. Further, because any

potential diagnostic utility is not yet known and has not yet been disclosed, the utility is not substantial because it is not currently available in practical form. Moreover, use of the claimed polypeptide or the encoding polynucleotides thereof in an array for drug screening is only useful in the sense that the information that is gained from the screening is dependent on the pattern derived from the array or profile for drug screening, and says nothing with regard to each individual member of the array or profile. Again, this is a utility which would apply to virtually every member of a general class of materials, such as any collection of proteins or DNA. Even if the expression of the claimed polypeptide or the encoding polynucleotides thereof is affected by a test compound in an array for drug screening, the specification does not disclose any specific and substantial interpretation for the result, and none is known in the art. Given this consideration, the claimed polypeptide and the encoding polynucleotides thereof have no "well-established" use. The artisan is required to perform further experimentation on the claimed material itself in order to determine to what "use" any expression information regarding the polypeptide could be put.

Further, with the lack of any correlation between the claimed polypeptide and the encoding polynucleotides thereof with any known disease or disorder, any information obtained from a screening assay would only serve as the basis for further research on the observation itself. "Congress intended that no patent be granted on a chemical compound whose sole 'utility' consists of its potential role as an object of use-testing." *Brenner*, 148 USPO at 696. The disclosure does not present a substantial utility that would support the requirement of 35 U.S.C. 101.

For reasons set forth above the disclosure satisfies none of the three criteria of utility requirements. *See In re Kirk*, 153 USPO 48, 53 (CCPA 1967) (quoting the Board of Patent Appeals, 'We do not believe that it was the intention of the statutes to require the Patent Office, the courts, or the public to play the sort of guessing game that might be involved if an applicant could satisfy the requirements of the statutes by indicating the usefulness of a claimed compound in terms of possible use so general as to be meaningless and then, after his research or that of his competitors has definitely ascertained an actual use for the compound, adducing evidence intended to show that a particular specific use would have been obvious to men skilled in the particular art to which this use relates').

The specification essentially gives an invitation to experiment wherein the artisan is invited to elaborate a functional use for the claimed polypeptides.

REJECTION UNDER 35 USC 112, FIRST PARAGRAPH, WRITTEN DESCRIPTION

The following is a quotation of the first paragraph of 35 USC 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 17-19 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to

reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 17-19 are drawn to a PS118 polypeptide having at least "50% identity" with an amino acid sequence selected from the group consisting of SEQ ID NO:27-31, and fragments thereof. Said polypeptide is produced by recombinant or synthetic techniques.

The polypeptides recited in claims 17- 19 encompass variants of the PS118 polypeptide of SEQ ID NO: 27-31. Further, it is noted there is no definition of PS118 polypeptide in the specification, other than a mere disclosure of "products of a prostate tissue gene designated as PS118" (p. 10, line 22. As written the claims encompass polypeptides unrelated to SEQ ID NO:27-31, with unknown structure, that has at least 50% identity with polypeptides unrelated to the claimed PS118 polypeptide that comprise SEQ ID NO:28-31, or fragments thereof. *Vas-Cath Inc. V. Mahurkar*, 19 USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the "written description" inquiry, *whatever is now claimed.*" (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (*See Vas-Cath* at page 1116).

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from its enablement provision (see page 115).

Although drawn to DNA molecules, the following teaching of the court is relevant to the claimed invention. In *The Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA..."requires a precise definition, such as by structure, formula, chemical name, or physical properties", not a mere wish or plan for obtaining the claimed chemical invention".

Support for variants is provided in the specification on pages 6 and 9 where it is disclosed that the invention encompasses variants having about 50% identity with SEQ ID NO:27, and on page 11 where it is disclosed that techniques for distinguishing amino acid "similarity" are known in the art. However, no disclosure of the structure of the claimed variants having 50% identity with SEQ ID NO:27-31. This is insufficient to support the generic claims as provided by the Interim Written Description Guildlines published in the June 15, 1998 Federal Register at Volume 63, Number 114, pages 32639-32645.

The instant specification fails to provide sufficient descriptive information, such as definitive common structural or functional features of the claimed genus of polypeptides.

The claims 17-19 read on polypeptide variants of SEQ ID NO:27-31, wherein said variants have any type of substitution besides conservative substitution, at any amino acid, throughout the length of the polypeptide, as well as insertions and deletions, provided that the resulted variation is up to 50% difference with SEQ ID NO:27. The specification and the claims do not disclose any limit on which amino acid that is subjected to conservative or non-conservative substitution, the type of substitution besides conservative substitution, nor the type of amino acids replacing the original amino acids. Thus the scope of the claims includes numerous structural polypeptide variants. The specification and the claims do not provide any guidance as to which, or how many original amino acid(s) that are naturally substituted, or to which type of substitution besides conservative substitution, or which amino acids that are naturally deleted or inserted so that the claimed polypeptide could function as contemplated. Structural features, that could distinguish the claimed structural polypeptide variants from the polypeptide sequences known in the art, are missing from the disclosure. No common structural attributes that identify the claimed structural polypeptide variants are disclosed. In addition, no common functional attributes that identify the claimed structural polypeptide variants are disclosed, because the function of a polypeptide sequence could be abolished, even with substitution of only one amino acid (Burgess et al. Journal of Cell Biology, 1990, 11: 2129-2138).

Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, the disclosure of a specific polypeptide sequence and the ability to screen, is insufficient to

describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe and enable the genus as broadly claimed.

Therefore only the isolated polypeptide of SEQ ID NO:27, and fragments thereof comprising SEQ ID NO:28-31, or an isolated polypeptide consisting of SEQ ID NO:28-31, but not the full breadth of the claims meets the written description provision of 35 USC 112, first paragraph.

REJECTION UNDER 35 USC 112, FIRST PARAGRAPH, ENABLEMENT

The following is a quotation of the first paragraph of 35 U.S.C. 112:

"The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention."

Claims 17-19 are rejected under 35 U.S.C. 112, first paragraph.

Specifically, since the claimed invention is not supported by specific, substantial utility or a well established utility for the reasons set forth in the rejection under 35 USC 101 above, one skilled in the art clearly would not know how to use the claimed invention.

REJECTION UNDER 35 USC 112, FIRST PARAGRAPH, SCOPE OF ENABLEMENT

If Applicant could overcome the above 101 and 112, first paragraph rejection, claims 17-19 are still rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the polypeptide of SEQ ID NO:27, does not reasonably provide enablement for polypeptide "variants" of the polypeptide of SEQ ID NO:27. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Claims 17-19 are drawn to a PS118 polypeptide having at least 50% identity with an amino acid sequence selected from the group consisting of SEQ ID NO:27-31, and fragments thereof. Said polypeptide is produced by recombinant or synthetic techniques.

Applicant has not shown how to make and use the claimed polypeptide variants which are capable of functioning as that which is being disclosed.

Protein chemistry is probably one of the most unpredictable areas of biotechnology. For example, replacement of a single lysine residue at position 118 of acidic fibroblast growth factor by glutamic acid led to the substantial loss of heparin binding, receptor binding and biological activity of the protein (Burgess et al. Journal of Cell Biology, 1990, 11: 2129-2138). In transforming growth factor alpha, replacement of aspartic acid at position 47 with alanine or asparagine did not affect biological activity while replacement with serine or glutamic acid sharply reduced the biological activity of the mitogen (Lazar et al. Molecular and Cell Biology, 1988, 8: 1247-1252). Similarly, it has been shown that aglycosylation of antibodies reduces the resistance of the

antibodies to proteolytic degradation, while CH2 deletions increase the binding affinity of the antibodies (see Tao. et al. The Journal of Immunology, 1989, 143(8): 2595-2601, and Gillies et al. Human Antibodies and Hybridomas, 1990, 1(1): 47-54). These references demonstrate that even a single amino acid substitution or what appears to be an inconsequential chemical modification will often dramatically affect the biological activity and characteristic of a protein.

In view of the above unpredictability, one of skill in the art would be forced into undue experimentation in order to perform the claimed invention as broadly as claimed.

In addition, although conservative substitution would not destroy the biological function of a protein, the specification fails to disclose which amino acid(s) are subjected to conservative substitution. In the absence of a source of method of making such variants, one of skill in the art would be forced into undue experimentation to practice the claimed invention as broadly as claimed.

REJECTION UNDER 35 USC 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 17-18 is rejected under 35 U.S.C. 102(b) as being anticipated by Girdham, CG et al, 1991, or Bork, P et al, 1993, GenBank Accession No: P34739, National Center for Biotechnology Information, National Library of Medicine, Bethesda, Maryland.

Claims 17-18 are drawn to a PS118 polypeptide having at least 50% identity with an amino acid sequence selected from the group consisting of SEQ ID NO:27-31, and "fragments" thereof. Said polypeptide is produced by recombinant technique.

It is noted that there is no definition of PS118 polypeptide in the specification, other than a mere disclosure of "products of a prostate tissue gene designated as PS118" (p. 10, line 22).

It is further noted the claimed fragment of a PS118 polypeptide encompasses a fragment comprising as little as one amino acid of a prostate tissue gene product.

US 6140468 prostate specific antigen produced by recombinant technique.

The reference does not specifically teach a PS118 polypeptide having at least 50% identity with a fragment of an amino acid sequence selected from the group consisting of SEQ ID NO:27-31. However, the claimed fragments appears to be the same as the prior art fragments. The office does not have the facilities and resources to provide the factual evidence needed in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed product is different from those taught by the prior art

and to establish patentable diffrences. See In re Best 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 703-305-2008. The examiner can normally be reached on 9:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ANTHONY CAPUTA can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0916.

SUSAN UNGAR, PH.D
PRIMARY EXAMINER

MINH TAM DAVIS

August 7, 2003